K122109

510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 21 2012

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA. 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

5. **Date Prepared:**
   July 12, 2012

6. **TRADE NAME(S):**
   Aquilion ONE Vision, TSX-301C/1, v4.90

7. **COMMON NAME:**
   System, X-ray, Computed, Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750)

9. **PRODUCT CODE / DESCRIPTION:**
   JAK – System, Computed Tomography

10. **PERFORMANCE STANDARD:**
    21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

11. **PREDICATE DEVICE:**
    Aquilion ONE TSX-301A/2, w/4.74ER
    K113466
    Toshiba America Medical Systems, Inc.

12. **REASON FOR SUBMISSION:**
    Modification of a cleared device

13. DEVICE DESCRIPTION:

The Aquilion ONE Vision, TSX-301C/1, v4.90 is a whole body CT scanner. This device captures cross sectional volume data sets. The device consists of a gantry, patient couch (table) and peripheral cabinets used for data processing and display.

14. SUMMARY OF INTENDED USES:

This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head, with the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, pancreas, etc.

The Aquilion ONE has the capability to provide volume sets of the entire organ. These volume sets can be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

15. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aquilion ONE, TSX-301A/2, w4.74ER, K113466, marketed by Toshiba America Medical Systems. The Aquilion ONE Vision, TSX-301C/1, v4.90, includes modifications to the cleared device which improve the scan time and view rates. The method of operation, base software and manufacturing process remain unchanged from the cleared device.

Summary of Changes from Aquilion ONE TSX-301A/2

Item	Aquilion ONE Vision, TSX-301C/1	Aquilion ONE TSX-301A/2
Gantry Rotational Speed	0.275 Seconds	0.35 Seconds
View Rate (number of views transferred per second)	2910	2572
X-ray Generator Output Power	90kW Maximum	70kW Maximum
X-ray Tube angle	10 degrees	11 degrees
Computer System	Quad Core Xeon based	Dual Core Xeon based
Image reconstruction (maximum speed)	50 images per second	30 images per second
Gantry Opening	780mm	720mm

1. Increased rotational speed from 350mS to 275mS
2. X-ray Generator is changed to match dose at new speed
3. Tube has hardware enhancements to allow for higher rotational speed
4. View rates have been increased

16. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 standards and its collateral standards. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

17. TESTING

Image Quality metrics utilizing phantoms are provided in this submission. Additionally, testing of the modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and CT Systems.

18. CONCLUSION

The modifications incorporated into the Aquilion ONE Vision, TSX-301C/1, v4.90 do not change the indications for use or the intended use of the device. Safety and effectiveness have been verified via risk management and application of design controls to the modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

SEP 21 2012

Re: K122109
Trade/Device Name: Aquilion ONE Vision, TSX-301c/1, v4.90
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 16, 2012
Received: July 17, 2012

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

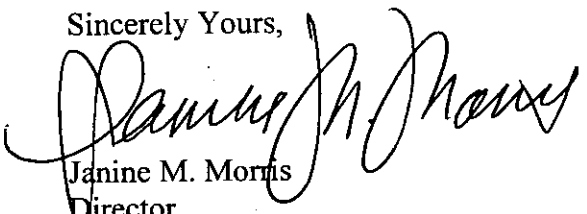
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Aquilion ONE Vision, TSX-301C/1, v4.90**

Indications for Use:

This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head, with the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, pancreas, etc.

The Aquilion ONE has the capability to provide volume sets of the entire organ. These volume sets can be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

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